UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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In re:

REZULIN PRODUCTS LIABILITY LITIGATION — MDL No. 1348

This paper relates to: All Cases. — Master File
00 Civ. 2843 (LAK)

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MEMORANDUM OPINION

Appearances:

Charles A. Mathis
HERMAN, MATHIS, CASEY & KITCHENS

Arnold Levin
LEVIN FISHBEIN SEDRAN & BERMAN

Melvin I. Weiss
Regina L. LaPolla
MILBERG WEISS BERSHAD HYNES & LERACH LLP

Ramon Rossi Lopez
LOPEZ, HODES, RESTAINO, MILMAN, SKIKOS & POLOS

Attorneys for Plaintiffs

David Klingsberg
Maris Veidemanis
Allan M. Pepper
Bert L. Slonim
Robert Grass
KAYE, SCHOLER, FIERMAN, HAYS & HANDLER, LLP

Attorneys for Defendants

LEWIS A. KAPLAN, *District Judge.*

Plaintiffs in this putative class action, which has been consolidated for pretrial purposes with hundreds of individual products liability actions, seek relief based upon their ingestion of the prescription drug Rezulin. The matter currently is before the Court on plaintiffs' motion to certify (1) a class of all persons who ingested Rezulin and their spouses,[1] and (2) a subclass of asymptomatic Rezulin users who have not manifested physical injury. The proposed class seeks, among other things, restitution of the revenues defendants realized from the sale of Rezulin and compensatory and punitive damages.[2] The proposed subclass seeks to create and fund a medical monitoring mechanism for those exposed to Rezulin.[3] For the reasons discussed below, the motion is denied.

I The Introduction and Withdrawal of Rezulin[4]

More than 15 million Americans suffer from Type II diabetes, commonly referred to as adult onset diabetes, a disease characterized by high blood-sugar levels which, if left untreated, can lead to coronary heart disease, blindness, kidney failure and limb amputation. Prior to 1996,

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1 Consolidated amended class action complaint ("Cpt") ¶ 123.

2 Cpt., prayer for relief ¶¶ c, d, f.

3 *See* Pl. Mem. at 1. The consolidated amended class action complaint makes no mention of the request for certification of a subclass.

4 Except as otherwise noted, the facts are taken from the consolidated amended class action complaint, the allegations of which are assumed true for purposes of this motion, and should not be construed as findings. *See, e.g., German v. Federal Home Loan Mortgage Corp.,* 885 F. Supp. 537, 547 (S.D.N.Y. 1995); *Maywalt v. Parker & Parsley Petroleum Co.,* 147 F.R.D. 51, 54 (S.D.N.Y. 1993).

treatment for this malady consisted primarily of multi-drug regimes and insulin injections.

In 1996, Warner-Lambert Company ("Warner-Lambert") announced the development of Rezulin,[5] a drug that it intended not only as a treatment for Type II diabetes, but also as a drug that might play a role in preventing the disease. The Food and Drug Administration (the "FDA") agreed to consider approving Rezulin on a priority basis, or within six months of Warner-Lambert's filing of a new drug application.

Rezulin ran into some obstacles in the course of its approval,[6] but the FDA ultimately approved it for sale to consumers, for use in conjunction with insulin therapy, on January 29, 1997, and Warner-Lambert began to sell it in the United States that March.[7] In August 1997, the FDA approved use of Rezulin as a monotherapy as well. Following the drug's market introduction, however, Rezulin encountered a series of problems.

The first occurred several months after Rezulin was first marketed, when Warner-

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5 The generic name is troglitzarone.

6 Most notable among the obstacles, perhaps, was the recommendation of Dr. John L. Gueriguian, M.D., who had been assigned by the FDA to oversee Rezulin's approval process, that approval be denied. Dr. Gueriguian reportedly told the *Los Angeles Times* that he felt Rezulin presented "a very high probability for severe liver toxicity" and that it "offered very little therapeutic advantage" over existing diabetes medications. Cpt. ¶ 29. Dr. Gueriguian was removed from the Rezulin review team and the FDA, maintaining that his report was not official because it was in draft form only, purged his report from its files.

7 In the initial press release concerning the launch of Rezulin, defendants asserted that "Rezulin is the first anti-diabetes drug to work at the cellular level to improve insulin resistance directly enhancing the effects of circulating insulin . . . . Until now other therapies lowered blood glucose by increasing insulin production or decreasing [liver] glucose output." Cpt. ¶ 59. The FDA accused Warner-Lambert of making "false and misleading claims" and recommended that Warner-Lambert "immediately discontinue" circulating the release, although it did not order Warner-Lambert to issue a corrective statement. *Id.* at ¶ 60.

Lambert received reports of patients who had experienced liver failure resulting in death or transplant while on Rezulin. The FDA subsequently required, in October 1997, that Warner-Lambert change the Rezulin label to recommend liver enzyme testing within the first one to two months and then every three months during the first year of therapy, and periodically thereafter. In December 1997, following a report that the United Kingdom was considering a ban on the sale of Rezulin, Glaxo-Wellcome, the holder of rights to market Rezulin in Great Britain, withdrew it from the market. Also in December 1997, the FDA required a second labeling change to recommend monthly liver enzyme testing for the first six months of Rezulin therapy, followed by tests every two months for the remainder of the first year and periodically thereafter. Then, on May 17, 1998, a non-diabetic participant in a Rezulin study died of irreversible liver failure shortly after undergoing a liver transplant, and an NIH physician concluded that her death had "'probably' been caused by Rezulin,"[8] although Warner-Lambert asserted that it was "apparently due to complications unrelated to" Rezulin.[9]

In July 1998, Warner-Lambert again was directed to revise the Rezulin label to recommend monthly liver testing for the first eight months of therapy, followed by a test every two months for the remainder of the first year and periodically thereafter. The FDA subsequently convened a second advisory committee to evaluate the safety of Rezulin, and in June 1999 the FDA adopted the committee's recommendation that Rezulin be permitted to remain on the market, but that

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[8] Cpt. ¶ 81.

[9] *Id.* at ¶ 83.

Rezulin was withdrawn from the study following her death.

it be approved for use only in combination with insulin and other medications and that it no longer be used as an initial therapy for treating diabetes. A new label advising patients to undergo monthly liver-function testing for the first twelve months of use and quarterly for the second twelve months was required.

The final straw appears to have been a March 10, 2000, *Los Angeles Times* report that the FDA had linked Rezulin to eighty-nine cases of liver failure, including sixty-one that resulted in death.[10] Twelve days later, Warner-Lambert withdrew Rezulin from the market.[11]

II Plaintiffs' Allegations

A. The Substantive Claims Relating to Rezulin

Plaintiffs here claim that Rezulin is both hepato- and cardiotoxic, *i.e.*, that it is toxic to the liver and the heart. Specifically, they assert that it is causally associated with a variety of liver and heart ailments, often asymptomatic, including (1) liver cell death and necrosis, (2) concomitant and chronic inflammation in the liver, (3) fibrosis, including bridging fibrosis, of the liver, (4) cirrhosis, (5) liver failure requiring transplant or resulting in death, (6) irreversible liver scarrring, (7) congestive heart failure, (8) fluid overload and retention in the cardiac muscle, (9) cardiomyopathy and (10) increased cardiac gross weight.[12] But it is useful to place this assertion in context.

As plaintiffs acknowledge, "[h]epatotoxicity is a known complication of most

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[10] *Id.* at ¶ 104.

[11] *Id.* at ¶ 106.

[12] Plaintiffs allege that two-thirds of all adverse event reports for Rezulin were heart failure related. *See* LaPolla Aff. Ex. 11.

prescribed drugs."[13] Other side effects also are common. And the claim is not that Rezulin caused liver or cardiopulmonary injury in all or even most who ingested it. On the contrary, even plaintiffs' experts agree that "the controlled clinical studies of the drug Rezulin demonstrate that the vast majority of patients who were treated with Rezulin tolerated the drug well and had no elevated liver enzymes and had no liver injury as a result of the drug."[14] Thus, while nothing turns on the proposition at this stage of the proceedings, it appears that such injuries, if any, as Rezulin caused may well have been both rare and idiosyncratic,[15] although this of course would not excuse any concealment of the risks of such injuries.

B. Class Allegations

The essence of the complaint is that the defendants failed adequately to disclose the risks of liver and cardiopulmonary complications.[16] Had they done so, the complaint alleges, the

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13 Pl. Mem. 12.

14 Day Dep. 232; Klein Dep. (*McCaffery*) 65-66.

The principal disagreement between plaintiffs and defendants on this score is whether the percentage of those taking Rezulin who suffered no liver injury was 95 percent, as plaintiffs maintain, or 98 percent, as defendants claim. *Compare* Day Dep. 232 (95%) *and* Klein Dep. (*McCaffery*) 65-66 (95%) *with* Watkins Decl. ¶ 9 (98%).

15 Watkins Decl. ¶¶ 12-15; Kaplowitz Decl. ¶ 6.

16 *See, e.g.,* Cpt. ¶¶ 118-22; Pl. Mem. 1 ("Because of the way in which Rezulin acts . . . , many users are at an increased risk . . . ."), 2 ("Defendants' wrongful acts . . . are the proximate cause of the increased risk of serious injury . . . .").

plaintiffs and, presumably, the other class members would not have taken the drug.[17] Having ingested Rezulin, however, plaintiffs and members of the class allegedly were damaged.[18] Plaintiffs seek relief on the following theories:

1. *Negligence*: Defendants allegedly failed to exercise reasonable care in the manufacture, sale, testing, quality control, marketing and distribution of Rezulin and this failure allegedly created a high risk of unreasonable, dangerous side-effects.[19]

2. *Fraud*: Defendants allegedly knew or should have known that Rezulin was dangerous and not as effective for its purpose as they represented and that it posed risks greater than were disclosed. Plaintiffs allege that defendants had a common law duty to disclose as well as a duty not to engage in false and deceptive trade practices.[20]

3. *Fraud on the FDA*: Defendants allegedly deceived the FDA, in violation of 18 U.S.C. § 1001, but for which Rezulin would not have been approved.[21]

4. *New Jersey Products Liability Act*:[22] Defendants' allegedly failed to warn the FDA of material facts regarding Rezulin's safety, as well as their allegedly inadequate testing and

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17 Cpt. ¶ 119.

18 *Id.* ¶¶ 144-45, 151, 160, 169, 174, 179, 188, 192, 197, 213, 215, 226.

19 Cpt. ¶¶ 140-45.

20 *Id.* at ¶¶ 146-51.

21 *Id.* at ¶¶ 152-60.

22 N.J. STAT. ANN. § 2A:58C-1 *et seq.*

warnings, which is said to have resulted in plaintiffs' injuries.[23] Plaintiffs allege also that Rezulin was a defective product within the meaning of the NJPLA because it was unreasonably dangerous, more dangerous than the ordinary consumer would expect and more dangerous than other Type II diabetes medications.[24]

5. *Strict Products Liability*: Defendants allegedly failed adequately to warn plaintiffs of the symptoms, scope and severity of the side effects of Rezulin and this failure to warn stemmed from the allegedly inadequate testing performed by the defendants.[25] Plaintiffs allege also that defendants are strictly liable because Rezulin was defectively designed.[26]

6. *Breach of Warranty*: Defendants allegedly breached both an express warranty of Rezulin's safety[27] and an implied warranty that Rezulin was safe and fit for the use for which it was sold.[28]

7. *New Jersey Consumer Fraud Act*:[29] Defendants are alleged knowingly to have

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23 Cpt. ¶¶ 161-69.

24 *Id.* at ¶¶ 175-79.

25 *Id.* at ¶¶ 170-74.

26 *Id.* at ¶¶ 180-88.

27 *Id.* at ¶¶ 189-92.

28 *Id.* at ¶¶ 193-97.

29 N.J. STAT. ANN. § 56:8-1 *et seq.* In the alternative, plaintiffs allege that "defendants' wrongful acts violated the consumer fraud and consumer protection statutes of the various states." Cpt. ¶ 223.

concealed, suppressed or omitted material facts concerning the dangers and risks associated with Rezulin and falsely and deceptively misrepresented information regarding the safety and efficacy of Rezulin in violation of the NJCFA. Plaintiffs assert that this entitles them to a refund of all moneys acquired by defendants as a result of these practices as well as treble damages for plaintiffs' ascertainable losses.[30]

8. *Medical Monitoring and Injunctive and Equitable Relief*: Defendants' alleged acts are said to have placed members of the class at an increased risk of serious injury and disease, a risk which necessitates periodic diagnostic and medical examinations. Plaintiffs assert that defendants should be required to pay for these examinations.[31]

9. *Unjust Enrichment*: Finally, defendants are said to have been enriched unjustly at the expense and to the detriment of the class members. Plaintiffs therefore seek restitution of their profits from the sale of Rezulin.[32]

III Class Certification

As the Supreme Court has noted, cases in which "individual stakes are high and disparities among class members great," "'ordinarily [are] not appropriate' for class treatment."[33] It

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30 Cpt. ¶¶ 198-221.

31 *Id.* at ¶¶ 224-37.

32 *Id.* at ¶¶ 238-41.

33 *Amchem Products, Inc. v. Windsor,* 521 U.S. 591, 625 (1997) (quoting Adv. Comm. Notes to the 1966 Revision of Rule 23(b)(3)).

therefore is not surprising that all relevant Court of Appeals[34] and the bulk of relevant district court decisions[35] have rejected class certification in products liability cases. Nor, for the same reason, is it surprising that state courts in both California and West Virginia have declined to certify classes in other Rezulin cases.[36] There is nothing about this case that warrants any different conclusion.

Plaintiffs seeking class certification bear the burden of demonstrating that the class and any subclass meet the four requirements of Rule 23(a) as well as one of the criteria of Rule 23(b). In this case, the Court assumes without deciding that the requirements of Rule 23(a) are satisfied. It

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34 *See Valentino v. Carter-Wallace, Inc.,* 97 F.3d 1227 (9th Cir. 1996) (reversing certification of pharmaceutical product liability case); *In re Am. Med. Systs., Inc.,* 75 F.3d 1069 (6th Cir. 1996) (vacating certification of class of penile prosthesis users); *Matter of Rhone-Poulenc Rorer, Inc.,* 51 F.3d 1293 (7th Cir.), *cert. denied,* 516 U.S. 867 (1995) (decertifying class of hemophiliacs infected by the AIDS virus as a result of using defendants' products); *In re Northern Dist. of Cal. Dalkon Shield IUD Prod. Liab. Litig.,* 693 F.2d 847 (9th Cir. 1982), *cert. denied,* 459 U.S. 1171 (1983).

35 *E.g., In re Propulsid Prod. Liab. Lit.*, 208 F.R.D. 133 (E.D. La. 2002) (drug); *Block v. Abbott Labs.*, No. 99 C 7457, 2002 WL 485364 (N.D. Ill. March 29, 2002); *Rosmer v. Pfizer, Inc.*, No. 9:99-2280-18RB (D.S.C. March 30, 2001) (drug); *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520 (N.D. Ill. 1998) (drug); *Woodell v. Procter & Gamble Mfg. Co.*, No. Civ. 3:96-CV-2723-H, 1998 WL 686767 (N.D. Tex. Sept. 29, 1998) (drug); *Fisher v. Bristol-Myers Squibb Co.*, 181 F.R.D. 365 (N.D. Ill. 1998) (drug); *Bradshaw v. Pfizer Inc.*, No. 1:93 CV 1619 (N.D. Ohio Oct. 31, 1997) (artificial hip); *Haley v. Medtronic*, 169 F.R.D. 643 (C.D. Cal. 1996) (pacemaker); *In re Norplant Contraceptive Prod. Liab. Lit.*, 168 F.R.D. 577 (E.D. Tex. 1996) (birth control device); *In re L-Tryptophan*, MDL No. 865 (D.S.C. 1996) (food supplement) (cited in *Barela v. Showa Denko K.K.,* 1996 WL 316544, *2 (D.N.M. 1996)); *Doe v. Mentor Corp.*, No. 94-2280 (E.D. La. July 22, 1996) (penile prostheses); *Harding v. Tambrands Inc.*, 165 F.R.D. 623 (D. Kan. 1996) (tampons); *Martin v. Am. Med. Sys., Inc.*, No. IP 94-2067-C-H/G, 1995 WL 680630 (S.D. Ind. 1995) (penile prostheses); *Miles v. Am. Med. Sys., Inc.*, No. C-94-1808 (N.D. Cal. March 3, 1995) (same); *Kurczi v. Eli Lilly & Co.*, 160 F.R.D. 667 (N.D. Ohio 1995) (DES); *In re Orthopedic Bone Screw Prod. Liab. Lit.*, MDL No. 1014, Civ. A. 93-7074, 1995 WL 273597 (E.D. Pa. Feb. 22, 1995) (pedicle screws).

36 *Delaney v. Warner-Lambert Co.,* No. BC 227414, slip op. at 14 (Cal. Sup. Ct., L.A. Co., filed Jan. 15, 2002); *In re West Virginia Rezulin Litig.,* No. 00-C-1180-H, 2001 WL 1818442 (W. Va. Cir. Ct., Raleigh Co., filed Dec. 13, 2001).

nevertheless is clear that the case is inappropriate for certification.

A. The Proposed Class – Rule 23(b)(3)

A class may be certified under Rule 23(b)(3) only if:

> "the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action."

Substantially all of these factors weigh heavily against the certification of a Rule 23(b)(3) class.

To begin with, the gist of plaintiffs' claims – even their design defect count – is that the defendants misled and failed adequately to warn members of the alleged class, their physicians, and the FDA concerning the risks inherent in the use of Rezulin and that many members of the class were damaged as a result. But these allegations, even at this broad level of generality, raise a host of individual issues.

Only some class members allege that they were injured by Rezulin, and their alleged injuries vary, with some claiming heart and others claiming liver injury. Others allege that their decedents died as a result of ingesting Rezulin. Many have suffered no physical injury whatsoever and complain only of the allegedly enhanced risk. Indeed, many class members, and their physicians, found Rezulin to be an extremely effective drug.[37]

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[37] Plaintiffs' experts assert that Rezulin was effective for 95 percent of the patients who ingested it. Day Dep. 232; Klein Dep. (*McCaffery*) 65-66.

Class members who allege a physical injury, were a class certified, would have to prove that Rezulin caused that injury. As one court noted, "[a]n assessment of specific causation . . . necessarily dissolves into a myriad of individualized causation inquiries."[38] And the individualized nature of the causation inquiries is not surprising, as class members took Rezulin at different times, for different periods, in different amounts, and while undergoing different levels of liver and other health monitoring. Moreover, although the fact that all class members presumably were diabetic appears to be a unifying circumstance, the issue whether Rezulin caused physical injury to a specific class member will depend on his or her unique characteristics such as family and medical background, preexisting medical conditions, age, gender, life style, drug or alcohol use, quantity of Rezulin ingested, duration of course of treatment, whether it was used as an initial therapy and whether Rezulin was used alone or in conjunction with other drugs.[39] Also of central importance would be questions concerning whether an individual plaintiff's doctor received any warnings regarding Rezulin and whether he or she heeded those warnings by, for example, properly weighing the risk factors and ordering the liver function monitoring recommended in the Rezulin product

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38 *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 208 F.R.D. 625, 632 (W.D. Wash. 2002).

39 *See, e.g., id.* at 631-32. Rezulin was approved for different uses (*i.e.* initial vs. follow-up and mono- vs. combination therapy) at different points during its time on the market. Additionally, the FDA required a series of label changes to Rezulin to reflect different recommendations regarding liver function monitoring. The other diabetes drugs on the market at the time also, like all prescription drugs, are hepatoxins. Whether a given plaintiff has taken one of these drugs and whether it could be the cause of that plaintiff's injury will be central to the liability inquiry.

literature, if any.[40] Additionally, class members would have to show that each doctor's decision to prescribe Rezulin would have been different had defendants issued what plaintiffs allege would have been proper warnings. Defendants' liability, if any, to an individual class member would depend also on whether the class member followed the directions that accompanied Rezulin and whether he or she exceeded the recommended dosage.[41] Moreover, the claims of many class members may be subject to individual defenses such as comparative or contributory negligence and the statute of limitations.[42] This situation is compounded by the fact that there were several changes in the labeling of Rezulin during its brief period on the market, thus altering the total mix of information available

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See In re Am. Med. Sys., Inc., 75 F.3d 1069, 1081 (6th Cir. 1996) (recognizing that the physician who treated each class member would be required to testify to the warnings, if any, he or she received and the warnings, if any, that in turn were passed on to the patient); *see also In re Orthopedic Bone Screws*, 1995 WL 273597, *11 n.13 ("To prevail on [causation], each plaintiff has the burden of showing that [the defendant] promoted/marketed its medical device to the plaintiff's particular doctor or surgeon for [that use], and that such promotion caused the surgeon to decide that surgical implantation of the particular device was the best procedure for improving plaintiff's condition.").

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And all of these individual issues would be present regardless of whether the Court must apply the law of one jurisdiction or of many.

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See, e.g., Barnes v. Am. Tobacco Co., 161 F.3d 127, 143 (3d Cir. 1998) (stating that "many individual issues" would be raised by comparative negligence defenses)*; In re Am. Med. Sys., Inc.*, 75 F.3d at 1085 ("Furthermore, the alleged tortfeasor's affirmative defenses (such as failure to follow directions, assumption of the risk, contributory negligence, and the statute of limitations) may depend on facts peculiar to each plaintiff's case"); *In re Northern Dist. of Cal. Dalkon Shield IUD Prod. Liab. Litig*, 693 F.2d at 853 (same).

The presence of individual defenses in this case cuts in exactly the opposite way as it did for the plaintiffs in *In re Agent Orange Prod. Liab. Lit.*, 818 F.2d 145 (2d Cir. 1987). There the Second Circuit expressed its doubt as to the presence of commonality, typicality and predominance of class-wide injury issues, but approved the certification of the class nonetheless. It held that the presence of the military contractor defense as a defense to the claims of every single plaintiff provided the requisite commonality, typicality, adequacy, predominance and superiority. There is no such common defense here.

during the various periods in which class members took the drug.

Individual questions would abound even with respect to class members who do not claim to have suffered any physical injury. Certainly the length of time they took the drug, the dosages they ingested, whether they were on other drugs at various points and most of the other factors alluded to above would be relevant to the extent, if any, of enhancement of their risks of developing future complications attributable to Rezulin.

Plaintiffs contend that a focus on causation of individual physical injuries would be misplaced and that the essence of their claim is the deception of class members and their physicians with respect to the risks of using Rezulin. New Jersey, they say, has dispensed with any requirement of proving reliance or causation in consumer fraud actions.[43] But this argument presupposes the universal applicability of New Jersey law, an assumption which, as shown below, is highly doubtful. In consequence, even if plaintiffs' attempt to recharacterize what at root is a product liability suit as one for consumer fraud otherwise were appropriate, the Court quite likely would be obliged to apply the laws of all fifty states to determine the need for proving such matters as intent, reliance, causation and injury before even addressing the form and extent of any relief that might be appropriate. Absent a contrary showing by plaintiffs, and they have attempted none, it appears entirely probable that even a consumer fraud theory would require individualized proof concerning reliance and causation, which are hornbook elements of a fraud claim,[44] as prerequisites to recovery by many and perhaps most of the members of the alleged class.

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[43] Pl. Mem. 46-48.

[44] *See generally, e.g.,* 2 FOWLER V. HARPER, FLEMING JAMES, & OSCAR S. GRAY, THE LAW OF TORTS c. 7 (1986).

Accordingly, while there no doubt are common questions concerning the characteristics of Rezulin and the manner in which FDA approval was obtained, individual questions, particularly but not limited to causation and reliance, overwhelm those common issues.[45]

Plaintiffs seek to circumvent this straightforward conclusion by focusing on their prayer for "restitution" of the purchase price and other supposedly equitable relief, thus supposedly avoiding individual determinations of damages. The argument, however, is a snare and delusion.

First, the complaint alleges damage to plaintiffs and class members and seeks compensatory damages for negligence, violation of the New Jersey Product Liability Act, and breach of warranty and on a theory of strict product liability. The pretense that there are no damage claims asserted on behalf of plaintiffs and class members is inconsistent with the pleading. But plaintiffs' argument would lack merit even if its premise – that the only monetary claim asserted is for restitution or, as plaintiffs' memorandum now prefers to call it, "disgorgement" – were correct.

In order to obtain restitution of the purchase price of Rezulin, plaintiffs and class members would be obliged, at least in many jurisdictions, to prove some kind of harm. In other words, although theories presumably could differ, they would have to establish that they were injured by detrimental reliance on a fraudulent or misleading statement, that the defendants' retention of the price they paid for the drug would be unjust, that the value of the drug given its allegedly concealed defects was less than the purchase price, or some other variation that would warrant the transfer of

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[45] Plaintiffs argue that since safety of the drug is the issue -- that is to say, no labeling change would have been effective -- no individualized issues are presented. But this simply is not the case. Without delving too deeply into the merits, plaintiffs have proffered nothing to support their contention that no label change would have been effective. In fact, the expert testimony offered by plaintiff indicates the opposite: Rezulin worked very well for at least 95 percent of those who used it. Day. Dep. 232; Klein Dep. (*McCaffery*) 65-66.

money from the defendants to them.[46] Every one of these theories would involve issues individual to the particular class member. The New Jersey Consumer Fraud Act,[47] upon which plaintiffs rely, for example, affords a right to monetary relief only if there has been an "ascertainable loss" in consequence of the "consumer receiv[ing] something other than what he bargained for . . . [and] los[ing] the benefits of the product which he was led to believe he had purchased."[48] Plaintiffs' contention that everyone who took Rezulin sustained an ascertainable loss presumes that Rezulin was worthless. But that is not a defensible position. Even plaintiffs' experts acknowledge that Rezulin was enormously beneficial to many patients.[49] Those patients presumably got their money's worth and suffered no economic injury. And the question whether an individual class member got his or her money's worth is inherently individual. Indeed, it involves very much the same questions as would a claim for money damages for personal injury.

Analogous individual issues arise regardless of the legal theory. Would the

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46 *See, e.g.*, *Holeman v. Neils*, 803 F. Supp. 237, 242 (D. Ariz. 1992); *Feitler v. Animation Celection, Inc.*, 170 Or. App. 702, 707-08, 13 P.3d 1044, 1047 (Or. Ct. App. 2000); *Rizzo v. Michener*, 401 Pa. Super. 47, 61, 584 A.2d 973, 979-80 (Pa. Super. Ct. 1990). *But see, e.g.*, *Podolsky v. First Healthcare Corp.*, 58 Cal. Rptr.2d. 89, 98-99 (Cal. Ct. App. 1996) (stating that proof of reliance is not required under California Unfair Competition Act).

47 N.J. STAT. ANN.§ 56:8-1 *et seq*.

48 N.J. STAT. ANN. § 56:8-19; *Miller v. Am. Fam. Pubs.,* 284 N.J. Super. 67, 87, 663 A.2d 643, 654 (App. Div. 1995).

It might be noted that the New Jersey Supreme Court appears not yet to have resolved the question whether the Act applies to prescription drugs and devices. In any case, the existence of the learned intermediary doctrine makes the determination whether a violation has occurred somewhat less than straightforward in prescription drug or device cases. *See Jones v. Sportelli*, 166 N.J. Super. 383, 39-0, 399 A.2d 1047, 1050 (1979).

49 Day. Dep. 232; Klein Dep. (*McCaffery*) 65-66.

defendants' retention of the price paid by class member X be "unjust"? It depends upon whether Rezulin benefited that individual and whether the benefits sufficiently outweigh any harm, even in the form of enhanced risk, that the individual sustained.[50] Was an individual defrauded? It depends, at least in many states, not only upon what was said by the defendants to the world at large, but upon whether the individual plaintiff knew of what was said and relied upon it.[51] And so on *ad infinitum.*

In the last analysis, then, the demand for restitution, or "disgorgement," of the purchase price solves nothing. Individual issues would predominate on a restitution claim even in the absence of any claims for compensatory damages.

Consideration of the other Rule 23(b)(3) factors only weakens plaintiffs' position. Those members of the class who in fact sustained physical injuries arguably attributable to Rezulin – in other words, those with real personal injury cases – obviously have an overwhelming interest in pursuing their own lawsuits rather than being submerged in a class seeking a refund of the purchase price of the drug. Indeed, there are more than 800 such cases in this Court, not to mention thousands in state courts around the country, a circumstance that both demonstrates the strong interest of those who may have been injured in pursuing their own claims and independently counsels against certification.

Finally, the proposed class doubtless includes members from all fifty states, and

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50 *See, e.g.*, *Admiral Plastics Corp. v. Trueblood, Inc.*, 436 F.2d 1335, 1339 (6th Cir. 1971); *Rivera v. Wyeth-Ayerst Labs.*, 121 F. Supp.2d 614, 620 (S.D. Tex. 2000).

51 *See, e.g., Broida v. McGlumphy*, C.A. No. 20975, 2002 WL 31015563 (Ohio Ct. App. Sept. 11, 2002); *Harold Cohn & Co., Inc. v. Harco Int'l, LLC*, No. 22093, 2002 WL 1987666 (Conn. App. Ct. Sept. 3, 2002); *Goss v. Bobby D. Assoc.*, No. 12-02-00020-CV, 2002 WL 2013083 (Tex. App. Aug. 26, 2002).

plaintiffs' claims overwhelmingly arise under state rather than federal law. This dictates that the claims of individual class members be decided under state law.[52] And this only compounds the problems noted already.

In determining what substantive law applies, federal courts apply the choice of law rules of the forum state[53] or, where the action has been transferred pursuant to Section 1404(a) or 1407 of the Judicial Code,[54] the choice of law rules applicable in the transferor court.[55] The initial issue therefore is the determination of the forum state or states.

Each of the ten individual plaintiffs was a plaintiff in an action commenced in another state and then transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to Section 1407. Each of those actions remains pending before this Court. Each of those plaintiffs then joined in the consolidated amended class action complaint, which of course was filed in this Court

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52 Plaintiffs invoke federal subject matter jurisdiction only on the theory of diversity of citizenship. Cpt. ¶ 6. Their claim of fraud on the FDA, which asserts that defendants owed a duty of candor to that agency by virtue of 18 U.S.C. § 1001, conceivably might be construed as raising a federal claim. As will appear, however, nothing turns on this.

53 It commonly is said that the *Erie* doctrine requires application of the forum state's choice of law rules in diversity cases, *see, e.g., Klaxon v. Stentor Elec. Mfg. Co., Inc.*, 313 U.S. 487 (1941), and it perhaps is arguable that this case is here under federal question as well as diversity jurisdiction. Note 52, *supra.* As the Second Circuit has held, however, it is not the basis of jurisdiction that requires application of the forum state's choice of law rules, but the source of the claim in question. *Maternally Yours, Inc. v. Your Maternity Shop, Inc.,* 234 F.2d 538, 540-41 n.1 (2d Cir. 1956); *accord* CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE: JURISDICTION 2D § 4520 (1996).

54 28 U.S.C. § 1414(a), 1407.

55 *See Ferens v. John Deere Co.,* 494 U.S. 516, 519 (1990) (§1404(a) transfer); *Van Dusen v. Barrack*, 376 U.S. 612, 639 (1964) (same); *Sheldon v. PHH Corp.,* 135 F.3d 148, 152 (2d Cir. 1998) (same); *Menowitz v. Brown*, 991 F.2d 36 (2d Cir. 1993) (§ 1407 transfer).

in the first instance.

There are two possible views of this situation. If one were to consider that the claim of each plaintiff in this consolidated class action was filed in the court in which that plaintiff commenced his or her individual suit, then the Court would be obliged to apply the choice of law rules of each of the relevant jurisdictions – here, California, Illinois, Louisiana, New Jersey, Ohio, Pennsylvania, and Puerto Rico – to determine the law that governs the claim of each. On the other hand, one might consider the entire consolidated class action as having been filed in New York because the consolidated complaint first was filed here.

Fortunately, it is unnecessary to decide this question. Even if one were to take the case as having been filed in New York and apply the New York choice of law rules, an assumption favorable to the plaintiffs because it would avoid the need for state-by-state choice of law analyses, the result would be unfavorable to class certification.

The New York choice of law analysis in tort cases is clear:

> "In tort actions, if there is a conflict of laws, New York courts apply an 'interests analysis,' under which the law of the jurisdiction having the greatest interest in the litigation is applied. *AroChem Int'l, Inc. v. Buirkle,* 968 F.2d 266, 270 (2d Cir. 1992); *see also Babcock v. Jackson,* 12 N.Y.2d 473, 481, 240 N.Y.S.2d 743, 191 N.E.2d 279 (1963). 'In deciding which state has the prevailing interest, we look only to those facts or contacts that relate to the purpose of the particular laws in conflict. "Under this formulation, the significant contacts are, almost exclusively, the parties domiciles and the locus of the tort."' *AroChem Int'l,* 968 F.2d at 270 (quoting *Schultz v. Boy Scouts of America, Inc.,* 65 N.Y.2d 189, 197, 491 N.Y.S.2d 90, 480 N.E.2d 679 (1985)). 'If conflicting conduct-regulating laws are at issue, the law of the jurisdiction where the tort occurred will generally apply because that jurisdiction has the greatest interest in regulating behavior within its borders.' *Cooney v. Osgood Mach., Inc.,* 81 N.Y.2d 66, 72, 595 N.Y.S.2d 919, 612 N.E.2d 277 (1993)."[56]

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[56] *Curley v. AMR Corp.,* 153 F.3d 5, 11 (2d Cir. 1998).

This case abounds with often difficult issues with respect to conduct-regulating laws. These include, but by no means are limited to, the standard governing strict liability claims against pharmaceutical manufacturers, the scope and impact of the learned intermediary doctrine, and the rules governing disclosure in the advertising of ethical pharmaceuticals. Critical liability questions therefore presumptively will be governed by the law of the states in which particular members of this million person putative class reside.[57]

Plaintiffs, no doubt recognizing the serious impediment to class treatment posed by a need to apply the laws of all or substantially all fifty states to class members' claims, nevertheless assert that New York choice of law principles permit the application of the substantive law of New Jersey to the claims of all class members, regardless of whether they are New Jersey domiciliaries. They contend that the interests of New Jersey, the manufacturer defendants' home state, in, *inter alia*, holding its corporate citizens accountable is so substantial that it trumps all other factors. But the Court disagrees. Competing against New Jersey's interest is that of every other state in ensuring that its own citizens are compensated for their injuries, that the standards its sets for product sales within its borders are complied with and that the rules it establishes to govern physician and pharmacist conduct are upheld. These interests simply are not outweighed by New Jersey's interest in regulating the conduct of its pharmaceutical companies.[58] Nor have plaintiffs made any serious attempt to

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57 New York courts consider the place where the drug was ingested to be the location of the tort. *See, e.g., Plummer v. Lederle Labs.*, 819 F.2d 349, 355 (2d Cir. 1987); *Ashley v. Abbott Labs*., 789 F. Supp. 552, 567-68 (E.D.N.Y. 1992); *In re New York Cty DES Actions*, 238 A.D.2d 172, 173, 655 N.Y.S.2d 520, 521 (1st Dep't 1997).

58 *See, e.g., Packer v. Kaiser Found. Health Plan of the Mid-Atlantic States, Inc.*, 728 F. Supp. 8, 11 (D. D.C. 1989). Nor are plaintiffs, nonresidents of New Jersey, entitled to any benefits of New Jersey law. *See Deemer v. Silk City Textile Mach. Co.*, 475 A.2d 648, 652 (N.J.

demonstrate that the case could be managed in any reasonable way, given the need to apply differing laws of the states concerned.[59]

The Court's analysis of the choice of law issue and its implications for the pending motion is confirmed by the Seventh Circuit's recent decision in *Matter of Bridgestone/Firestone, Inc.,*[60] a case that plaintiffs predicted at oral argument – prior to the Circuit's decision – would "be a beacon for many state court class actions."[61] The plaintiffs in that case, which involved the highly publicized controversy that ensued upon the allegedly widespread failure of Bridgestone/Firestone tires used on Ford Explorer vehicles, obtained certification of nationwide classes of owners and lessees of Ford Explorers and of certain Bridgestone/Firestone tires. Like the plaintiffs here, they sought to avoid individual issues of causation and injury by framing the actions as suits for consumer fraud and breach of warranty, seeking recovery for the allegedly enhanced risk that tires on class

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App. Div. 1984) ("[T]here is no compelling reason for us to extend to such non-domiciliary plaintiffs the benefit of our decisional law."). To be clear, the Court is not holding that a non-New Jersey plaintiff can never benefit from New Jersey law or that New Jersey has an interest in ensuring that foreign plaintiffs do not benefit from its laws, but rather that, as compared to the interests of other states in protecting their plaintiffs, New Jersey does not have an interest in expanding its laws to cover foreign plaintiffs.

59 "[P]laintiffs b[ore] the burden of providing an 'extensive analysis' of state law variations to determine whether there are 'insuperable obstacles' to class certification." *In re Ford Motor Co. Ignition Switch Products Liab. Litig.*, 174 F.R.D. at 332; *see also Walsh v. Ford Motor Co.*, 807 F.2d 1000, 1017 (D.C. Cir. 1986). Attempts at such "extensive analysis" often include model jury instructions and verdicts forms, as well as an attempt to group state laws by their relevant differences. Plaintiffs made no such showing here, despite being challenged in defendants' answering brief to do so, except to say that they would be prepared to do so should the Court rule against them on this point, Pl. Mem. at 45, an assertion that was too little, too late.

60 288 F.3d 1012 (7th Cir. 2002).

61 Tr., Aug. 6, 2001, at 45.

members' vehicles would fail. But the Seventh Circuit reversed. It first held that, under the forum state's choice of law rules, the laws of the various states in which the class members resided would govern.[62] Most states, it concluded, do not permit recovery for the sort of financial injury of which plaintiffs complained – the enhanced risk of product failure – when "tort law fully compensates those who are physically injured."[63] In any case, it observed, "[s]tate consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules."[64] And it held that "[b]ecause these claims must be adjudicated under the law of so many jurisdictions, a single nationwide class is not manageable."[65] This of course is another way of saying that the individual issues arising by virtue of the multiplicity of varying state laws predominated over the common issues. So too here.

There is a good deal more that could be said, but the foregoing is sufficient. The Court finds that individual questions of fact and law predominate with respect to the alleged class, that the interest of members of the class in individually controlling the prosecution of claims is paramount and that very serious difficulties would be encountered in managing the putative class action were it certified. The Court therefore declines to certify the proposed class.

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62 *Matter of Bridgestone/Firestone, Inc.*, 288 F.3d. at 1016-17.

63 *Id.* at 1017.

64 *Id.* at 1018.

65 *Id.*

B. The Proposed Subclass – Rule 23(b)(2)

Plaintiffs seek also to certify a medical monitoring subclass under Rule 23(b)(2), which makes certification appropriate where Rule 23(a) is satisfied and the "party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole."[66] The parties lock horns on virtually every aspect of this Rule, but it is unnecessary to discuss all of the points they raise.

1. Applicability of Rule 23(b)(2)

The consolidated class action complaint seeks compensatory and punitive damages as well as the establishment and funding of a medical monitoring mechanism and other relief. The first question therefore must be whether plaintiffs may invoke Rule 23(b)(2) at all, given the presence of the damage claims. The framework for analysis of this issue is the Second Circuit's recent decision in *Robinson v. Metro-North Commuter R.R. Co.*[67]

The question in *Robinson* was whether the presence of non-incidental damage claims in a Title VII employment discrimination class action *ipso facto* precluded certification of a (b)(2) class with respect to plaintiffs' claim for injunctive relief. In concluding that it did not, the Court established the controlling standard:

> "[W]e hold that when presented with a motion for (b)(2) class certification of a claim seeking both injunctive relief and non-incidental monetary damages, a district court

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66 FED. R. CIV. P. Rule 23(b)(2).

67 267 F.3d 147 (2d Cir. 2001).

> must 'consider[] the evidence presented at a class certification hearing and the arguments of counsel,' and then assess whether (b)(2) certification is appropriate in light of 'the relative importance of the remedies sought, given all of the facts and circumstances of the case.' *Hoffman,* 191 F.R.D. at 536. The district court may allow (b)(2) certification if it finds in its 'informed, sound judicial discretion' that (1) 'the positive weight or value [to the plaintiffs] of the injunctive or declaratory relief sought is predominant even though compensatory or punitive damages are also claimed,' *Allison,* 151 F.3d at 430 (Dennis, *J.,* dissenting), and (2) class treatment would be efficient and manageable, thereby achieving an appreciable measure of judicial economy.
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> "Although the assessment of whether injunctive or declaratory relief predominates will require an ad hoc balancing that will vary from case to case, before allowing (b)(2) certification a district court should, at a minimum, satisfy itself of the following: (1) even in the absence of a possible monetary recovery, reasonable plaintiffs would bring the suit to obtain the injunctive or declaratory relief sought; and (2) the injunctive or declaratory relief sought would be both reasonably necessary and appropriate were the plaintiffs to succeed on the merits. Insignificant or sham requests for injunctive relief should not provide cover for (b)(2) certification of claims that are brought essentially for monetary recovery."[68]

The question whether the claim for medical monitoring, which the Court assumes without deciding seeks an equitable remedy that comes within the rule, predominates over the claims for monetary relief is not an easy one. It certainly is not predominant for those class members who have suffered physical injury, allegedly as a result of Rezulin. But the subclass is defined to exclude such persons. Hence, the money the members of the subclass seek to recover would constitute damages for consumer fraud or restitution of the amounts they paid for the drug. In consequence, in order to determine whether damages or the medical monitoring program is the predominant relief sought, it would be necessary to know something about how the costs of medical monitoring would compare to the revenues the defendants derived from selling Rezulin.

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[68] 267 F.3d at 164.

According to plaintiffs, defendants derived over $2.1 billion from the sale of Rezulin.[69] The record, however, is silent as to the cost of the proposed medical monitoring program[70] or its value to individual class members. In consequence, it is impossible to tell which form of relief is more important, or more valuable, to the proposed subclass members. This becomes even clearer when one considers that many subclass members are being monitored by their treating physicians for reasons unrelated to Rezulin.[71] As the burden on this issue, as on all issues going to the propriety of class certification, lies with the plaintiffs,[72] they fail right at the outset. But that is not the only reason they fail the test articulated in *Robinson.*

First, *Robinson* requires that the Court satisfy itself, "at a minimum," that reasonable plaintiffs would sue for the medical monitoring program sought here even in the absence of a claim for damages. This must require a determination that a reasonable plaintiff, based on a medical and economic calculus, would have sued solely for a medical monitoring program, not merely that a lawyer could have been found who would have located a plaintiff and brought a class action in the hope of a fee, else the test would be meaningless.

Plaintiffs have not persuaded the Court that this criterion has been satisfied here. Neither the American Diabetes Association nor the American Association of Clinical Endocrinologists, which promulgate guidelines for the care and treatment of diabetics, nor any public

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69 Pl. Mem. 3 n.4.

70 *See* Cpt., Pl. Mem., Pl. Reply Mem.

71 *See infra* notes 78-79.

72 *See, e.g., Caridad v. Metro-North Commuter R.R.*, 191 F.3d 283, 293 (2d Cir. 1999).

health agency or professional medical society or institution, has recommended special monitoring for patients who formerly took Rezulin.[73] As plaintiffs' expert, Dr. Day, testified, the question whether an individual patient should be monitored is a matter for determination by each clinician in light of the patient's medical profile.[74] Indeed, plaintiffs' experts take the view that medical monitoring in essence would be a research project. Dr. Klein testified that the proposed medical monitoring "is a means by which . . . a test or experiment or study might be conducted" in order to test his "hypothesis that there are additional injuries" caused by Rezulin.[75] Dr. Bonkovsky, in a similar vein, said that the scientific jury is still out on the "question of whether Rezulin is, in fact, an important factor in the development and/or progression of liver disease" and that medical monitoring, in the form of "careful study of these patients, with case control" was appropriate to answer it.[76] Thus, the Court is not convinced that medical monitoring, at least on a class- or subclass-wide basis, is medically indicated.[77] Even if it were, the evidence shows that many patients formerly on Rezulin already are having blood chemistry tests, including liver studies, performed, in some cases, as part of their routine

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73 Vigersky Decl. ¶ 15; Watkins Decl. ¶¶ 17-18; Brennan Decl. ¶¶ 8-9.

74 Day Dep. 145.

75 Klein Dep. (*McCaffery*) 98-99.

76 Bonkovsky Dep. 186-87.

77 Furthermore, there is a lively dispute between plaintiffs' and defendants' experts about whether any problems that may be induced by Rezulin disappear with the cessation of administration of the drug, a point that is unnecessary to resolve at this juncture. *Compare, e.g.*, Day Decl. ¶¶ 13-14; Klein Decl. ¶ 9; *and* Smith Decl. ¶¶ 16-17 *with* Brennan Decl. ¶¶ 7, 9; Kaplowitz Decl. ¶ 8; Sonnenblick Decl. ¶ 23; *and* Watkins Decl. ¶¶ 10-11, 16, 21.

medical care and, in other cases, because the labels for the two newer diabetes drugs that replaced Rezulin so recommend.[78] For example, physicians treating at least some of the plaintiffs now give their patients periodic liver function tests, not because of prior Rezulin use, but because they were switched to these new drugs and/or because they routinely do so for all their diabetic patients.[79] In short, it is so far from clear that informed physicians, unaffected by litigation considerations, would recommend routine monitoring on the basis of former Rezulin use that the Court cannot conclude that a medical monitoring action would be rationally justified in the absence of a significant claim for damages or, for that matter, that medical monitoring would be an appropriate remedy even if plaintiffs prevailed.

Second, the Court is persuaded that a medical monitoring class action would not be sufficiently manageable or efficient. The availability of and prerequisites to medical monitoring are issues governed by state law. For precisely the reasons articulated earlier, the Court would be obliged to apply the laws of each of the fifty states to the claims of members of the putative subclass. As *Bridgestone/Firestone* makes clear, that would be unmanageable in most circumstances. It would be especially so here. Many states never have recognized a claim for medical monitoring, a circumstance that would force this Court into the undesirable position of attempting to predict how their courts of last resort would resolve that issue. Those states that have done so have adopted widely varying criteria for recovery.[80] There simply is no justification for embarking on so complex a path.[81]

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78 Kaplowitz Decl. ¶ 10; Watkins Decl. ¶ 23; Vigersky Decl. ¶ 15.

79 Aycinena Dep. 11; Furukawa Dep. 153; Tavani Dep. 107-08.

80 *See generally Georgine v. Amchem Prods., Inc.,* 83 F.3d 610, 627 (3d Cir. 1996), *aff'd sub nom. Amchem Prods., Inc. v. Windsor,* 521 U.S. 591 (1997); *Badillo v. Am. Brands, Inc.*,

Accordingly, the Court holds that plaintiffs have failed to establish the applicability of Rule 23(b)(2) to the proposed subclass.

2. The Requirements of Rule 23(b)(2) Are Not Satisfied

Even if Rule 23(b)(2) properly might be invoked with respect to the subclass, plaintiffs have failed to satisfy its requirements.

The first problem is that it is impossible by any practical means to determine who is in the proposed subclass. Plaintiffs define it as "all users of Rezulin who are presently asymptomatic

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No. 34300, 2001 WL 79884, 16 P.3d 435, 441 (Nev. 2001); *Dhamer v. Bristol-Myers Squibb Co.,* 183 F.R.D. 520, 533 (N.D. Ill. 1998); Slonim Decl. Ex. 21.

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Nor is it clear that the universal application of New Jersey law, even if that were appropriate, would render a (b)(2) class action manageable.

Under New Jersey law, medical monitoring is a remedy. *See Theer v. Philip Carey Co.*, 133 N.J. 610, 627, 628 A.2d 724, 733 (1993). The members of the subclass therefore would have to establish defendants' liability on a conventional theory. For the reasons discussed above with respect to the predominance of individual questions of fact and law, this could not be done on a class-wide basis and therefore would involve a plethora of individual questions. In any case, New Jersey has made the remedy of medical monitoring available as "a special compensatory remedy designed to address the unique harm entailed in an increase risk of future injury arising from the exposure to toxic chemicals." *Id.* This Court should not reach out for an opportunity to perform the New Jersey Supreme Court's function of deciding whether to extend that remedy to the ingestion of prescription drugs. Furthermore, the New Jersey court has stressed that medical monitoring is available "only if a plaintiff reasonably shows that medical surveillance is required because the exposure caused a distinctive increased risk of future injury, and would require a course of medical monitoring independent of any other that the plaintiff would otherwise have to undergo." *Id.* The Court is not so persuaded in this case. *See supra* notes 76-77. In any event, because the subclass members are diabetics under the care of physicians, plaintiffs have not demonstrated that they require a course of monitoring independent of their current treatments. *Supra* notes 78-79; Watkins Decl. ¶ 24.

and have not manifested physical injury."[82] But the questions whether an individual is asymptomatic or has manifested physical injury can be determined only by a physician. And "[a] class definition that calls for a 'medical conclusion' based on 'plaintiff-specific information' is 'an improper basis for maintaining a class action.'"[83]

Second, the individual issues that defeat the predominance requirement of Rule 23(b)(3) also pose an obstacle to class certification in the Rule 23(b)(2) context.[84] "At base, the (b)(2) class is distinguished from the (b)(3) class by class cohesiveness . . . . Injuries remedied through (b)(2) actions are really group, as opposed to individual injuries. The members of a (b)(2) class are generally bound together through 'preexisting or continuing legal relationships' or by some significant

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Pl. Mem. 1. In their reply brief, plaintiffs further narrow the definition of the subclass to "all people who have ingested Rezulin and have not clinically presented with liver disease." Pl. Reply Mem. 17.

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Def. Mem. at 5 (quoting *Newton v. Southern Wood Piedmont Co.*, 163 F.R.D. 625, 632 (S.D. Ga. 1995), *aff'd*, 95 F.3d 59 (11th Cir. 1996)); *accord Daniels v. City of New York*, 198 F.R.D. 409, 414 (S.D.N.Y. 2001).

In re Diet Drugs Prod. Liab. Litig., No. CIV. A. 98-20626, 1999 WL 673066, at * 16 (E.D. Pa. Aug. 26, 1999), in which the court conditionally certified a class of individuals who had taken diet drugs and not yet filed suit--a class definition requiring no medical conclusion--is not to the contrary. Moreover, plaintiffs' reliance on *Elliott v. Chicago Housing Auth.*, No. 98C 6307, 2000 WL 263730, at * 15 (N.D. Ill. Feb. 28, 2000), is misplaced. In that case, the court certified a medical monitoring class of children who resided in Section 8 housing and tested with elevated blood-lead levels. *Id*. Unlike in the instant case, which would require subjective evaluations by physicians concerning whether putative class members have manifested "physical injury," *Elliott* class members were easily identifiable by resort to an objective test.

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See, e.g.,Santiago v. City of Philadelphia, 72 F.R.D. 619, 628 (E.D. Pa. 1976) ("[T]he court should be more hesitant in accepting a (b)(2) suit which contains significant individual issues than it would under subsection 23(b)(3).").

common trait such as race or gender."[85] "The (b)(2) class action is intended for cases where broad, class-wide injunctive or declaratory relief is necessary to redress a group-wide injury."[86] In short, although there is no predominance or superiority requirement under Rule 23(b)(2), classes certified pursuant to it must be cohesive.

The subclass proposed here does not have the requisite level of cohesion. To be sure, plaintiffs allege that defendants' actions in developing, marketing and studying the drug constituted similar treatment with respect to all class members. But the prerequisites to, and the availability *vel non* of, medical monitoring vary from state to state and therefore among the members of the subclass. Even where medical monitoring may be available in defined circumstances, the need and desire of individual subclass members for such a remedy varies considerably.[87] As indicated previously, one of plaintiffs' experts testified that "it's up to each clinician to decide whether he wants to put his patients through a monitoring program or not."[88] In short, the individual issues presented here

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85 *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 143 n.18 (3d Cir. 1998) (quoting *Holmes v. Continental Can Co.*, 706 F.2d 1144, 1155 n.8 (11th Cir. 1983) (quoting Note, *Notice in Rule 23(b)(2) Class Actions for Monetary Relief:* Johnson v. Gen. Motors Corp., 128 U. PA. L. REV. 1236, 1252-53 (1980)).

86 *Robinson*, 267 F.3d 147, 162.

87 *See, e.g., Smith v. Brown & Williamson Tobacco Corp.*, 174 F.R.D. 90, 97 (W.D. Mo. 1997) (stating that entitlement to medical monitoring "depends upon an individualized showing of future risk, making resolution of this issue inappropriate for class-wide resolution"); *Werlein v. U.S.*, 746 F. Supp. 887, 912 (D.Minn. 1990), *vacated in part on other grounds*, 793 F. Supp. 898 (D. Minn. 1992) ("Such proof [of individual plaintiff's increased risk of harm] is not workable in a class action format."); *Brown v. SEPTA*, Civ. A. Nos. 86-2229, 86-4037, 86-5886, 1987 WL 9273, *13 (E.D. Pa. Apr. 9, 1987) ("Any entitlement to [medical monitoring] relief will depend on individualized questions of causation and personal medical history.").

88 Day Dep. 145.

undermine plaintiffs' claim of cohesion.

As was true with respect to Rule 23(b)(3), more could be said. But the foregoing is sufficient. The Court is unpersuaded that Rule 23(b)(2) is properly invoked here or, if it is, that its requirements are satisfied.

IV Conclusion

If Rezulin and its marketing was as bad as plaintiffs claim, defendants doubtless will get their comeuppance in the hundreds or thousands of personal injury cases already pending against them. These plaintiffs, however, have not satisfied the requirements of Rule 23. Their rhetoric affords no basis for an unjustified stretch to fit this square peg of a lawsuit into a round hole.

Plaintiffs' motion for class certification is denied in all respects.

SO ORDERED.

Dated: September 12, 2002

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Lewis A. Kaplan
United States District Judge